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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/595,326	06/16/2000	Nickolai Alexandrov	2750-942P	8710

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EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/23/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/595,326

Applicant(s)

ALEXANDROV ET AL.

Examiner

Monika B Sheinberg

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 25-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Response to Amendment A***

Applicants' arguments, filed 08 March 2002 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-51 are pending. Claims 25-50 remain withdrawn from consideration.

***Claim Rejections - 35 USC § 112 and 101***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 and 51, as necessitated by amendment, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejections are maintained as set forth in the previous office action mailed: 24 August 2001, and for the same reasons with respect to the new claim 51. The claims now recite particular subsequences of gi number 1297184. However, applicant(s) has not provided any direct description of these subsequences nor the sequence formed by their concatenation. The specification as filed is defective.

At best this is an attempt to incorporate essential subject matter into this application by reference to descriptive information available in the GenBank entry. It is improper because the gene 0 of the gi number 1297184 is essential material to describe the claimed nucleic acid sequences. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. The examiner was unable to find any clear statement of an intent to incorporate this sequence or the entire GenBank entry by reference in

the specification. If basis for such incorporation exists, applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-24 and 51, as necessitated by amendment, are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well-established utility.

The rejections are maintained as set forth in the previous office action mailed: 24 August 2001, and for the same reasons with respect to the new claim 51. The multiple subsequences of the elected gene 0 of the gi number 1297184 amended into the claims, remain without a specified or well-established utility. Nowhere in the specification are these selected subsequences disclosed as to having a specific utility per subsequence selected. Only a reference to the subsequences, including those not selected, is disclosed in the table.

Applicant(s) argue that Table 1 contains the gi number which "is fully associated in GenBank with specific information about the gene(s) contained within it" (amendment A, p.3). As described above, Table 1 only references the gi number and particular subsequences of the full sequence entered in GenBank. The GenBank entry describes specific gene information of the specific sequence in the data entry; it does not describe the utility of the particular exon combinations in the claims or the non-selected exon listed in the table. In addition, GenBank entries are not static, being subject to updates in both sequence and annotation, the specific nucleotide locations selected for the combination are thus also subject to change. Please see accession number print-outs provided. As per the revision history, the sequence entered for the

gi number 1297184 was first entered May 6, 1996. However NCBI has at the bottom of the page that the entry had been "Revised: October 24, 2001". It is uncertain what the revision entails; whether the information and sequence as now no longer pertain to the same gi number. The annotations can vary in addition with the information describing the entry. In addition, the entries do not provide a description of the utility of the sequence entry for a "gene 0" either. So it is unclear as to where the utility relied upon by applicant for gene 0 is described if it was described. For example, the gi number 1297184 entry has no annotations that indicate a gene 0 at the nucleotide base location beginning at position 9717 and ending at 11137 (besides gap location specifics). Thus it is unclear as to what the applicant regards as the instant invention if the sequences are not the same and the database entry is not static.

The following is a quotation of the *second* paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-24 and 51, as necessitated by amendment, are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejections are maintained as set forth in the previous office action mailed: 24 August 2001, and for the same reasons with respect to the new claim 51. Applicant(s) argue that the definition of "complement" is a "sequence in a polynucleotide chain in which all the bases are able to form base pairs with a sequence of bases in another polynucleotide" as per the Oxford Dictionary. However, the independent claims 1-3 and 51 are interpreted to comprise fragments of a complement, and not only full complements. Thus this encompasses even a single nucleotide since a fragment of a complement remains inclusive of a sequence of shorter length with each base pair matched with the base pairs of the resulting pieced together sequence recited in the claims. Thus the arguments are non-persuasive.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4 and 51, as necessitated by amendment, are rejected under 35 U.S.C. § 102(e) as being unpatentable over SEQ ID 1 or SEQ ID 2 of the US 5,992,554.

Any single nucleotide of the inherent mRNA sequence of reference SEQ IDs 1 or 2 suggests or motivates a fragment of a complement of the nucleotide sequence of claims 1-4 and 51. A single base from SEQ ID NO 1 or 2 of US 5,992,554 can form a base pair with a nucleotide base of the polynucleotide pieced together from gi number 1297184.

Therefore, the arguments are non-persuasive to overcome the rejection.

### ***Specification Objections***

The disclosure remains objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form or browser-executable code. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Such code is present in the specification at page 54, lines 28 and 29; and elsewhere.

Appropriate correction is required.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### *Inquiries*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 21, 2002

Monika B. Sheinberg  
Art Unit 1631

*MBS*

*Marianne P. Allen*  
[Stamp: RECEIVED, MAY 21 2002, PTO, ART UNIT 1631]  
*AU 1631*